

Applicants: David Pinsky, David Stern, and Shi-Fang Yan
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drawn to a method for reducing damage or vascular injury to an ischemic tissue by contacting cells of the tissue with an organic or inorganic compound as an inhibitor of Egr-1 protein, classified in class 514, subclass 1.

II. Claims 1, 3, 5-7 and 9-27, allegedly drawn to a method for reducing damage or vascular injury to an ischemic tissue by contacting cells of the tissue with a nucleic acid sequence (antisense sequence) as an inhibitor of Egr-1 protein, classified in class 514, subclass 44.

III. Claims 1, 4, 5, 7-14, 16-19, 21-25 and 27, allegedly drawn to a method for reducing damage or vascular injury to an ischemic tissue by contacting cells of the tissue with a peptide as an inhibitor of Egr-1 protein, classified in class 514, subclass 2.

IV. Claims 1, 4, 5, 7-14, allegedly drawn to a method for reducing damage to an ischemic tissue by contacting cells of the tissue with an antibody as an inhibitor of Egr-1 protein, classifiable in classes 424 and 514, subclasses 134.1 and 1.

The Examiner alleged that claims 1, 7 and 9-14 link inventions I-IV. The Examiner alleged that claims 4 and 8 link to inventions I, III and IV. The Examiner alleged that claims 5, 16-19, 21-25 and 27 link to inventions I-III. The Examiner alleged that the restriction requirement among the linked inventions is subject to the nonallowance of the linking claims,

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i.e. claims 1, 4, 5, 7-14, 16-19, 21-25 and 27. The Examiner stated that upon allowance of the linking claims the restriction requirement as to the linked claims shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. The Examiner stated that applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. The Examiner stated that where a restriction requirement is withdrawn, the provisions of 35 U.S.C. §121 are no longer applicable. The Examiner stated that the alleged inventions are distinct, each from the other because of the following reasons: The Examiner alleged that inventions I-IV are unrelated. The Examiner stated that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP §806.04, MPEP §808.01). The Examiner alleged that in the instant case the different inventions have different modes of operation and have different functions. The Examiner alleged that inventions I-IV are distinct because they are drawn to methods using different materials having different chemical structures, different physical properties and different biological functions: organic or inorganic compounds, nucleic acids, peptides, and antibodies. The Examiner alleged that they are materially distinct methods

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which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. The Examiner alleged that the differences between inventions I-IV are further underscored by their different classifications and independent search status. The Examiner alleged that therefore they are patentably distinct from each other. The Examiner alleged that because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

The Examiner stated that applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

The Examiner stated that applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. The Examiner stated that any amendment of inventorship must be accompanied by a petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(I).

In response, applicants undersigned attorney, on behalf of applicants, hereby elects, with traverse, to prosecute the invention of Examiner's group II, i.e. claims 1, 3, 5-7 and 9-27,

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allegedly drawn to a method for reducing damage or vascular injury to an ischemic tissue by contacting cells of the tissue with a nucleic acid sequence (antisense sequence) as an inhibitor of Egr-1 protein, classified in class 514, subclass 44.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction of Examiner's Group II from Examiner's Groups I and III-IV be withdrawn in view of the fact that the claims of Examiner's Group II are not independent of Examiner's Groups I and III-IV. Applicant maintains that the claims of Examiner's Group II and Examiner's Groups I and III-IV do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group II, allegedly drawn to a method for reducing damage or vascular injury to an ischemic tissue by contacting cells of the tissue with a nucleic acid sequence (antisense sequence) as an inhibitor of Egr-1 protein, is related to Examiner's groups I and III-IV in that all groups are directly related to a method for reducing damage or vascular injury to an ischemic tissue via specific inhibition of the Egr-1 protein signaling pathway.

The claims of Examiner's Group II, allegedly drawn to a method

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for reducing damage or vascular injury to an ischemic tissue by contacting cells of the tissue with a nucleic acid sequence (antisense sequence) as an inhibitor of Egr-1 protein, are related to the claims of Examiner's Groups I and III-IV, allegedly drawn to a method for reducing damage or vascular injury to an ischemic tissue by contacting cells of the tissue with an organic or inorganic compound, a peptide or an antibody as an inhibitor of Egr-1, respectively, because of the reliance of all identified claims of Groups I, III and IV on the use of an inhibitor of the Egr-1 protein signaling pathway as part of their design, operation, and effect. The specification recites that "these data provide insight into a previously unidentified role for Egr-1 as a master switch regulating a range of effector mechanisms underlying ischemic stress." See page 48, lines 23-25. Further, the specification recites that "deletion of the Egr-1 gene strikingly diminished expression of these mediators of vascular injury in a murine model of lung ischemia/reperfusion, and enhanced animal survival and organ function." See page 39, lines 20-23. Therefore, Examiner's Groups I-IV, allegedly drawn to a method for reducing damage or vascular injury to an ischemic tissue by contacting cells of the tissue with an organic or inorganic compound, a nucleic acid sequence (antisense sequence), a peptide, or an antibody as an inhibitor of Egr-1, all utilize the specific inhibition of the Egr-1 protein signaling pathway as part of their design, operation, and effect. Accordingly, applicants request that the Examiner examine Groups I-IV on the merits.

Applicant therefore respectfully contend that two or more

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independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group II, claims 1, 3, 5-7, and 9-27 allegedly drawn to a method for reducing damage or vascular injury to an ischemic tissue by contacting cells of the tissue with a nucleic acid sequence (antisense sequence) as an inhibitor of Egr-1 protein, will reveal whether any prior art exists as to inhibition of Egr-1 protein by an organic or inorganic molecule (Examiner's Group I), a peptide (Examiner's Group III) and an antibody (Examiner's Group IV). Since there is no burden on the Examiner to examine Groups I-IV in the subject application, the Examiner must examine the entire application on the merits.

Applicant maintains that claims 1-27 define a single inventive concept. Accordingly, applicant respectfully requests that the



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